Exhibit 22

缬沙坦原料药（国外规格）召回方案

Protocol of Valsartan API Recall (Foreign grade)

文件编号	**Document Number**	**RC-18002**
版本号	**Version**	**01**
编写部门	**Preparation Dept.**	质量管理部
保管部门	**Safekeeping Dept.**	质量管理部

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ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

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	版本号 Version： 01

方案审批表

Review and Approval Form

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一、 背景介绍 Background

2018 年 6 月 6 日，公司接到 Novartis 客户反馈，在 Novartis 第三方实验室检测缬沙坦原料药残留溶剂时，发现甲苯峰后的未知杂质峰，经过 GC-MS 鉴定疑似可能为 N-亚硝基二甲胺 N-Nitrosodimethylamine 杂质（NDMA 杂质）。

On June 6th 2018, Huahai was informed by customer Novartis that an unknown impurity peak eluting after the peak of Toluene was observed, while customer contracted a third part laboratory to test the residual solvents of Valsartan. The impurity was later suspected as N-Nitrosodimethylamine (NDMA) by GC-MS analysis.

接到客户信息后，公司质管部立即向公司质量负责人汇报，并立即组织生产部、技术部、分析部门等展开调查，通过调查公司确认部分缬沙坦原料药批次检出 NDMA 杂质，于 2018 年 06 月 20 日出具客户告知函（见附件 1），通知客户暂停使用公司提供的缬沙坦原料药。出于产品质量安全风险防范的考虑，公司于 2018 年 07 月 20 日出具客户退货告知函（见附件 2），同意客户将库存的在复验期内的缬沙坦原料药进行退货处理。

Upon receiving the information from customer, Corporate QA reported to the QP of Huahai immediately. And Production Dept., Technical Dept. and QC, QR, etc. were organized by Corporate QA to conduct an investigation immediately. By investigation, it is confirm that NDMA impurity was detected in some Valsartan API batches. On June 20 2018, a Notification Letter (see Annex 1) was issued to related customers to put on hold the use of Valsartan API. Considering the prevention of product quality risk, Huahai issued another Notification Letter (see Annex 2) to related API customers to request the return the stock of Valsartan API within retest period.

为了确保客户库存的在复验期内的缬沙坦原料药均能退回公司，现计划组织召回。涉及召回详细原因调查、措施制定已经在偏差调查（DCE-18001）中包含，不再包含在本方案中。

To ensure all the Valsartan API batches within retest period in customers' warehouse can be returned to Huahai, it is planned to conduct recall. Because the root cause investigation and measures to be taken have been included in the deviation investigation report (DCE-18001), it is no longer included in this protocol.

二、召回范围 Recall Scope

基于前期已发出客户退货告知函，同时结合产品各规格的复验期（复验期为 4 年）已与客户进行沟通，确定召回范围为客户库存的在复验期范围内的缬沙坦产品，即我公司 2014 年

6 月份-2018 年 6 月份生产的缬沙坦各规格库存产品需退回（若客户有 2014 年 6 月份前生产的批次库存，需双方协商后退回），根据以上原则客户反馈了退货产品信息，我公司经过核实最终确定的召回信息见附件 1。

Since Notification Letter had been issued to related customer previously and the retest period of Valsartan API was 4 years, after communication with the customers, it was determined to recall Valsartan API within the retest period. That is, Valsartan API (each grade) manufactured from June 2014 to June 2018 will be recalled (if the customer has batch stocks produced before June 2014, negotiation is needed before product return). According to the above principles, the information of product to be returned back had been summarized then verified by Huahai. For the final recall information, please refer to Annex 1.

三、职责 Responsibilities

1、公司质管部 Corporate QA Department：

- ✧ 负责跟进客户召回/退货信息的反馈；
- ✧ 负责起草召回方案、完成产品召回调查评估报告、编制召回总结报告并存档记录；
- ✧ 负责召回全过程的异常情况处理和监督工作。

Follow up the feedback of customer recall/return information;

Draft recall protocol, complete product recall investigation and evaluation report, draft recall summary report and archive records;

Handle anomaly and supervise the entire recall activity.

2、分子公司质管部 Site QA：

- ✧ 组织召回工作，对召回产品进行验收（对数量、批号、包装情况等进行核查）；
- ✧ 负责对纠正措施的跟踪检查，并收集相关资料。

Organize the recall action and conduct inspection and acceptance of the recalled products (check the quantity, batch number, packaging, etc.);

Follow up CAPA and assemble related documents.

3、销售部门 Sales Department：

- ✧ 负责通知客户，与客户沟通并反馈客户退货信息；
- ✧ 根据批准的召回方案做好产品的召回工作。

Responsible for informing customer, communicating with customer and feed back to customer；

Arrange the return process of product according to the approved recall protocol.

4、仓库 Warehouse：

✧ 负责隔离所有库存批次；

✧ 建立隔离库对召回的缬沙坦 API 进行接收、核查及保管工作，根据退货管理程序（SMP-012）做好产品后续处置。

Responsible for quarantine of all inventory batches;

Establish quarantine warehouse to receive, check and keep the recalled Valsartan API, and the follow-up of products according to the return management procedure (SMP-012).

5、生产部/技术部、QC/QR 及车间 Production & Technical Department, QC/QR and Workshop：

✧ 根据产品处置方案参与召回产品的分析和处理工作。

Participate in the analysis and handling of recalled products according to the product disposal plan.

6、公司质量负责人 QP：

✧ 负责召回过程的总体协调；

✧ 负责批准产品召回调查评估报告、召回方案及召回总结报告。

Responsible for the overall coordination of the recall process;

Responsible for approving investigation and evaluation report of product recall, recall protocol and recall summary report.

四、召回小组建立 Assemble the recall team

召回小组成员：由企业负责人、企业质量负责人、企业生产负责人及分厂厂长、销售负责人、川南分厂东厂区 QA、川南分厂西厂区 QA、销售部门、仓库人员等组成。

Team member: President, QP, Head of Production, Plant Director, Head of Sales Dept., QA of Chuannan Site East Zone, QA of Chuannan Site West Zone, Sales Dept. and Warehouse Dept.

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五、召回等级评定及召回时限 Grade evaluation and recall time limit

5.1 召回等级评定：Grade evaluation:

N-亚硝基二甲胺 N-Nitrosodimethylamine(NDMA)，在 IARC 的分类中被归为 2A 类，是半挥发性的有机化学物质，会以很低的水平存在在一些食品中，根据 WHO 的报告，成年人中，合理的最大环境日吸入量/日暴露量为 0.126 ug/kg。根据动物的致癌研究推测，NDMA 对动物来说有可能是致癌的，但是对于人的致癌性不明确；NDMA 的日暴露限度或许可以定为 1.5 ug/天，对于缬沙坦来说，最大剂量为 4.69ppm。基于对 NDMA 毒理学水平以及相对较短的暴露时间（不超过 5 年）的研究，可以推断缬沙坦药物产品对患者健康的总体风险影响是很小的。基于以上综合评估，将本次召回级别定义为二级召回。

N-Nitrosodimethylamine (NDMA) is classified as 2A in IARC and it is a semi volatile organic chemical substance which presents at very low levels in certain foodstuffs. According to WHO's report, the reasonable maximum daily inhalation/daily exposure of adults is 0.126ug/kg. According to animal carcinogenesis studies, NDMA may be carcinogenic to animals, but the carcinogenicity of humans is not clear.The daily exposure limit of NDMA may be set at 1.5ug/days. For Valsartan, the maximum dose is 4.69ppm. Based on studies of NDMA toxicological levels and relatively short exposure times (no more than five years), it can be inferred that Valsartan products have little impact on patient health. Based on the above comprehensive assessment, the recall level is defined as Grade 2.

5.2 召回时限：Recall Time Limit

按照公司 SMP-013 产品召回管理程序的规定，同时结合本事件发生的风险性，拟定销往国外市场的产品在召回方案批准后 90 日内完成召回，因路途遥远、交通运输等问题造成无法在规定时间内完成召回的，需要确定召回完成日期并且每日跟踪进展。

According to the provision of “SMP-013 Product Recall Management System”, and considering the risk of this incident, the products sold abroad will be recalled within 90 days after the approval of the recall plan. If the recall cannot be completed within the prescribed time due to the long distance, transportation and other problems, the recall date should be determined and keep track of progress every day.

六、召回流程 Recall Program

6.1 根据客户退货信息，由公司质管部起草召回方案，并组织建立召回小组，方案经召回小组人员审核，QP 批准后实施。

Based on the customer returns information, a recall protocol shall be drafted by Corporate QA. And a recall team shall be organized. The protocol can only be implemented after reviewed by the recall team and approved by QP.

6.2 召回方案批准后，1 个日历日内由公司质管部填写“产品召回调查评估报告 Q/ZHH JG-151”；复印件发放销售部门和仓库部门（原件 QA 保存）。

After the approval of the recall protocol, "Q/ZHH JG-151 Product recall investigation and evaluation report" shall be filled in by Corporate QA within one calendar day and distribute the copies to the sales department and the warehouse department (The original copy will be kept by QA).

6.3 销售部门接到“产品召回调查评估报告 Q/ZHH JG-151”后，根据产品召回的有关信息，在一个日历日内核实召回范围内的所有客户均已经通知到位并要求收货单位组织退回缬沙坦原料药。

After receiving"Q/ZHH JG-151 Product recall investigation and evaluation report", Sales Department shall confirm whether all related customers had been informed within one calendar day, and customers will be requested to organize the return of concerned Valsartan API.

6.4 仓库接到“产品召回调查评估报告”后，及时对退回缬沙坦 API 产品进行验收，隔离存放；并做好“退货检查和处理记录表 Q/ZHH JG-189”。

After receiving "Q/ZHH JG-151 Product recall investigation and evaluation report", warehouse should accept the returned valsartan API products in time, and quarantine them. "Q/ZHH JG-189 return inspection and processing record" shall be filled in correspondingly.

6.5 注意事项与其他要求：产品召回过程中，销售部门、公司质管部、川南分厂东厂区、西厂区质管部应对召回工作进展情况进行跟进（包括召回数量与规定量的差额等内容），公司质管部负责召回全过程的异常情况处理和监督工作。

Notes and other requirements: In the process of product recall, the progress (including the difference between actual quantity recalled and the intended quantity) and anomaly should confirmed and discussed by Sales Department, Corporate QA, QA of Chuannan Site, etc. Corporate QA is responsible for handling anomaly and supervising the whole recall process.

七、召回总结及产品处置 Summary of Recall and Product Handling

在召回工作完成后，公司质管部结合召回方案，对召回的及时性、召回平衡率等方面进行评估，并对召回效果进行评价；完成召回总结报告；召回的产品后续根据相应的处置方案进行后续处置。

After the recall is completed, timeliness and reconciliation of recall shall be evaluated by Corporate QA. Corporate QA shall also evaluate the effect of the recall and completes the summary report. The recalled product shall be handled according to the corresponding disposal plan.

八、参考资料 Reference

8.1 产品召回管理程序 SMP-013.07 SMP-013.07 Product Recall Management System

8.2 偏差调查报告 DC_E-18001 Deviation Investigation Report DC_E-18001

九、附件 Appendix

附件 1：客户告知函

Annex 1 Notification Letter

附件 2：客户退货告知函

Annex 2 Notification Letter regarding return of Valsartan API

附件 3：缬沙坦（国外规格）原料药召回清单

Annex 3: The recall list of Valsartan (Foreign grade)